

**APPENDIX N BULK MILK TANKER SCREENING TEST FORM**

**IDEXX - PARALLUX™ BETA LACTAM ASSAYS**

**GENERAL REQUIREMENTS**

1. See Appendix N General Requirements form items 1-8 & 13 \_\_\_\_\_
- a. Room temperature where test performed controlled to 18-29C (64-84F) \_\_\_\_\_

**SAMPLES**

2. See Appendix N General Requirements (GR) form item 9 \_\_\_\_\_

**APPARATUS & REAGENTS**

3. Equipment \_\_\_\_\_
- a. Parallax™ Processor \_\_\_\_\_
- b. Parallax™ Kit including cartridge and reagent tray \_\_\_\_\_
- Lot # \_\_\_\_\_
- Exp Date \_\_\_\_\_
1. Store kits at 0-7C (32-45F), tests may be kept at room temperature 18-29C (64-84F) during day of use \_\_\_\_\_
- c. Fixed volume pipettor to dispense 100 µL (see App. N GR item 7) \_\_\_\_\_
- d. Parallax™ Wash Solution and Wash Priming Tube \_\_\_\_\_
- e. Parallax™ Processor thermal paper \_\_\_\_\_
4. IDExx Parallax™ Positive Controls (Parallax™ Penicillin G/Cephapirin/Ceftiofur and Parallax™ Cloxacillin) \_\_\_\_\_
- a. Store according to label \_\_\_\_\_
- Lot # \_\_\_\_\_
- Exp Date \_\_\_\_\_
- b. Re-hydrate and use according to the package insert \_\_\_\_\_
1. Stored at 0-7C and used within 8 days \_\_\_\_\_

## 5. IDEXX Parallax™ Negative Control

a. Negative Controls must be run in duplicate daily prior to testing samples and with each new lot of product

b. Store according to label

Lot #

Exp Date

c. Re-hydrate and use according to the package insert

1. Stored at 0-7C and used within 8 days

### TECHNIQUE

## 6. Daily Performance (+/- Controls) and Operation Check (see App. N GR item 10)

a. Prime the Processor daily to remove any air bubbles, use only Parallax Wash Solution

b. First time use of a lot of test kits (item 3b), Processor will prompt the one time scanning of a series of barcodes to initialize the lot in the Processor software

c. In addition, negative Controls must be run in duplicate daily to standardize and ensure that the kits and Processor are performing accurately

1. The Processor prompts the daily running of the Negative Controls in duplicate

2. One of the two Negative Controls may be used in conjunction with the Positive Control for the daily performance check

## 7. Test Procedure

a. Processor power must be "ON"

b. At the Main Menu, press **1.Test**

c. Scan barcode located on the individual foil package associated with the current lot of product

**[Note: The system may provide incorrect analytical results if the incorrect barcode is scanned.]**

1. Use correct barcode \_\_\_\_\_
2. Scan each individual foil package prior to running a test \_\_\_\_\_
- d. Press **1.RunTest** \_\_\_\_\_
- e. Enter User ID and Sample Ids **[Required]** \_\_\_\_\_
- f. Mix sample/controls by shaking 25 times in 7 sec through 1 ft arc, use within 3 minutes \_\_\_\_\_
- g. Setup the cartridge, tray, and samples \_\_\_\_\_
  1. Place the reagent tray on the lifter \_\_\_\_\_
  2. Secure the cartridge on the connector \_\_\_\_\_
  3. Pipette 100  $\mu$ L of sample into each well of the reagent tray **[NOTE: If all four wells are not filled, test results are invalid and the sample must be rerun.]** \_\_\_\_\_
  4. Press **OK** to continue \_\_\_\_\_
  5. After the automated mixing, sipping, incubation and washing steps, move the cartridge from the Prep Station to the Read Station \_\_\_\_\_
  6. Open door, align and secure the cartridge on the pins, close door and press **OK** \_\_\_\_\_
8. Interpretation **[Note: The Processor dries and reads the cartridge then prints the results.]** \_\_\_\_\_
  - a. The Processor automatically prints results as "N" negative **(Not Found, NF)** or "P" positive \_\_\_\_\_
  - b. The results for each channel are followed by a ratio \_\_\_\_\_
    1. A negative result is any reading  $\leq 1.00$  \_\_\_\_\_
    2. A positive result is any reading  $> 1.00$  \_\_\_\_\_
9. Confirmation of Presumptive Positive Samples, **performed by certified analyst or CIS at direction of State Regulatory Agency** (see App. N GR item 11) \_\_\_\_\_
  - a. Use Parallax Beta-lactam Cartridge \_\_\_\_\_

- b. Scan the barcode on the individual foil package associated with the current lot of product

**[NOTE: Correct barcode must be used. The system may provide incorrect analytical results if the incorrect barcode is scanned.]**

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- 1. Each individual foil package must be scanned prior to running the test

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- c. Setup the cartridge, tray and samples and run test as indicated in item 7g 1-6

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#### 10. Reporting (see App. N GR item 12)

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